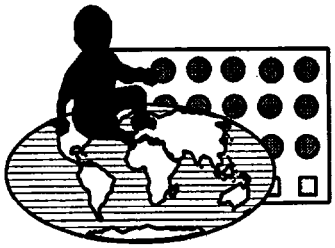

# Newborn Screening Quality Assurance Program

## PROFICIENCY TESTING PROGRAM FOR ANTI-HIV-1 IN DRIED BLOOD SPOTS

Quarterly Report | Quarter 2 | May 2006

### INTRODUCTION

The Anti-HIV-1 proficiency testing (PT) panel for Quarter 2 consisted of five individual-matrix dried-blood spot (DBS) specimens representing a variety of serostatuses. For the second quarter of 2006, we received data reports for 43 anti-HIV-1 PT panels from 39 participants. This report is the outcome of data reported for the anti-HIV-1 PT specimens that were received from participants by the designated deadline date. This quarterly report is distributed to all participants and to program colleagues by request. Each participant is asked to analyze the specimens for anti-HIV-1 using the assay schemes they routinely use and to report for each specimen the screening results along with results from any confirmatory assays performed for reactive screens.

### PARTICIPANTS' RESULTS

Participants conducting screening analysis reported no misclassifications for this quarter. All but one laboratory conducting confirmatory analyses identified the reactive specimen 2461 correctly. The one laboratory reported specimen 2461 as indeterminate.

In Part 1 of the report, Table 1 shows the number of laboratories using each screening method/kit; Table 2 shows the expected results and the number of laboratories reporting reactive and non-reactive results; and Table 3 summarizes EIA absorbance ranges and means by specimen number and method of analysis (representative data are shown for three kits). Table 3 also shows the results obtained by CDC.

In Part 2 of the report, Table 4 shows the number of laboratories using each confirmatory method/kit; Table 5 shows the expected results, number of laboratories reporting reactive, non-reactive, or indeterminate results; and the number of laboratories not reporting confirmatory results. Table 6 shows the band classifications by method of PT specimens that tested positive for HIV-1 initially and after repeat EIA analysis (representative data are shown for three methods). Table 6 also shows the results obtained by CDC.❖

The Quality Assurance Program will ship next quarter's HIV-1 DBS proficiency testing specimens on July 17, 2006, and the next major allotment of HIV-1 DBS quality control specimens on July 17, 2006.❖

### CONFERENCES

1st Annual African HIV/AIDS Clinical Update and Leadership Development Conference 15 to 16 June 2006. Panafric Hotel, Nairobi, Kenya. website: http://www.valleyaids.org

The XVI International AIDS Conference will be held August 13-18, 2006, in Toronto, Ontario, Canada. It is the world's largest, most comprehensive HIV/AIDS conference. The theme will be "Time to Deliver." Website: http://www.aids2006.org

*SpotLight*

**Training opportunity**

Assuring the Quality of HIV Prevention Counseling: Practical Approaches for Supervisors

City: Philadelphia, PA, August 1-3, 2006 or St. Louis, MO September 12-14, 2006 Sponsor: Centers for Disease Control & Prevention (CDC), Division of HIV/AIDS, Prevention Capacity Building Branch.

Contact: For additional information or to register access the Website at www.cdc.gov/hiv/cba/ or contact Theresa Folsom by phone: 404-639-0982.❖

Quarterly publication for colleagues and participants of the Performance Evaluation Program for Anti-HIV-1 in Dried Blood Spots.

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# Quarter 2, 2006

## PART 1. SCREENING

Table 1.
Screening Methods

| Kit Source | Total Participants |
|---|---|
| Genetic Systems *r*LAV EIA (Bio-Rad) | 9 |
| bioMerieux Vironostika HIV-1 Microelisa System | 11 |
| bioMerieux Vironostika Uni-Form II *plus* O | 7 |
| Fujirebio Serodia-HIV | 2 |
| Abbott Murex HIV 1+2 Gacelisa | 1 |
| Murex HIV 1.2.0 | 3 |
| Tecnosuma (Cuba) UMELISA HIV 1+2 | 0 |
| Other | 9 |
| In House | 1 |
| Total | 43 |

Table 2.
Number of Labs Reporting Screening Results

| Specimen Number | Expected Results | Reactive | Non-reactive | No Interpretation |
|---|---|---|---|---|
| 2641 | Reactive | 43 | 0 | 0 |
| 2642 | Non-reactive | 0 | 43 | 0 |
| 2643 | Non-reactive | 0 | 43 | 0 |
| 2644 | Non-reactive | 0 | 43 | 0 |
| 2645 | Non-reactive | 0 | 43 | 0 |

Table 3.

| Kit Source | | Specimen Number 2641 | 2642 | 2643 | 2644 | 2645 | Cutoff Value |
|---|---|---|---|---|---|---|---|
| Genetic Systems CDC Results | Range | 1.459-1.876 | 0.044-0.163 | 0.035-0.110 | 0.036-0.129 | 0.058-0.219 | 0.268-0.306 |
| | Mean | 1.698 | 0.104 | 0.079 | 0.096 | 0.130 | 0.280 |
| | | 1.812 | 0.167 | 0.155 | 0.225 | 0.268 | 0.297 |
| bioMerieux Vironostika CDC Results | Range | 2.287-2.739 | 0.270-0.378 | 0.226-0.298 | 0.254-0.350 | 0.272-0.395 | 0.464-0.519 |
| | Mean | 2.287 | 0.270 | 0.226 | 0.254 | 0.272 | 0.464 |
| | | 2.244 | 0.235 | 0.195 | 0.200 | 0.223 | 0.429 |
| bioMerieux Vironostika Uni-Form II *plus* O | Range | 1.003-1.945 | 0.057-0.158 | 0.055-0.158 | 0.051-0.197 | 0.059-0.178 | 0.148-0.207 |
| | Mean | 1.346 | 0.093 | 0.096 | 0.108 | 0.111 | 0.183 |

Use of trade names and commerical sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

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# Quarter 2, 2006

## PART 2. CONFIRMATORY

Table 4.
Confirmatory Methods

| Kit Source | Total Participants |
|---|---|
| Genetic Systems HIV-1 WB (Bio-Rad) | 15 |
| Bio-Rad New LAV Blot I | 3 |
| OraSure HIV-1 WB Kit | 2 |
| Genelab Diagnostics HIV 2.2 WB | 1 |
| Cambridge Biotech HIV-1 WB Kit (Calypte) | 1 |
| In House | 1 |
| Other | 1 |
| Total | 24 |

Table 5.
Number of Labs Reporting Western Blot Results

| Specimen Number | Expected Results | Reactive | Non-reactive | Indeterminate | Not Tested |
|---|---|---|---|---|---|
| 2641 | Reactive | 22 | 0 | 1 | 0 |
| 2642 | Non-reactive | 0 | 7 | 0 | 17 |
| 2643 | Non-reactive | 0 | 7 | 0 | 17 |
| 2644 | Non-reactive | 0 | 7 | 0 | 17 |
| 2645 | Non-reactive | 0 | 7 | 0 | 17 |

Table 6.

Specimen 2641

| Methods | gp160 | | gp120 | | p66 | | p55 | | p51 | | gp41 | | p31 | | p24 | | p18 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - |
| CDC (GS HIV-1 Kit, Bio-Rad) | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| Genetic Systems HIV-1 Kit (Bio-Rad) | 15 | 0 | 15 | 0 | 9 | 6 | 13 | 2 | 10 | 5 | 12 | 3 | 5 | 10 | 15 | 0 | 13 | 2 |
| Bio-Rad New LAV Blot I | 2 | 1 | 1 | 2 | 1 | 2 | 3 | 0 | 1 | 2 | 1 | 2 | 1 | 2 | 2 | 1 | 3 | 0 |
| OraSure HIV-1 WB Kit | 2 | 0 | 2 | 0 | 1 | 1 | 0 | 2 | 1 | 1 | 2 | 0 | 0 | 2 | 2 | 0 | 2 | 0 |

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This *NEWBORN SCREENING QUALITY ASSURANCE PROGRAM* report is an internal publication distributed to program participants and selected program colleagues. The laboratory quality assurance program is a project cosponsored by the **Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories.**


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